

### **REMARKS/ARGUMENTS**

Applicants have carefully reviewed the Final Office Action mailed on June 19, 2009. Applicants respectfully traverse all objections, rejections, and assertions made by the Examiner. Claims 1-4, 6-34, 43, 73-78, and 82-96 remain pending and have been rejected. Favorable consideration of the following remarks is respectfully requested.

#### **Claim Rejections under 35 U.S.C §103**

Claims 1-4, 6-18, 20-29, 31, 33, 34, 43, 73-78, 82-84, and 88-96 were rejected under 35 U.S.C. §103(a) as being unpatentable over Grayzel et al. (U.S. Patent No. 6,942,680) in view of Vigil et al. (U.S. Patent No. 5,336,234) and Campbell et al. (U.S. Patent No. 5,458,572).

Claims 30 and 85-87 were rejected under 35 U.S.C. §103(a) as being unpatentable over Grayzel et al. (U.S. Patent No. 6,942,680) in view of Vigil et al. (U.S. Patent No. 5,336,234) and Campbell et al. (U.S. Patent No. 5,458,572) as applied to claims 1, 14, and 43 above, and further in view of Roychowdhury (U.S. Patent No. 5,587,125).

Claim 32 was rejected under 35 U.S.C. §103(a) as being unpatentable over Grayzel et al. (U.S. Patent No. 6,942,680) in view of Vigil et al. (U.S. Patent No. 5,336,234) and Campbell et al. (U.S. Patent No. 5,458,572) as applied to claim 14 above, and further in view of Spears (U.S. Patent No. 5,082,841). These rejections are respectfully traversed.

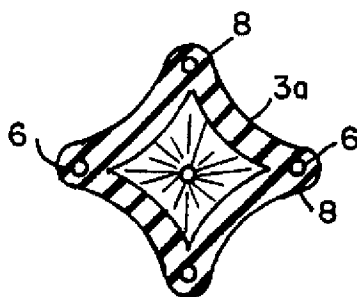
"All words in a claim must be considered in judging the patentability of that claim against the prior art." *In re Wilson*, 424 F.2d 1382, 1385, 165 USPQ 494, 496 (CCPA 1970). If an independent claim is nonobvious under 35 U.S.C. 103, then any claim depending therefrom is nonobvious. *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988). (MPEP 2143.03).

The Examiner admits that Grayzel et al. do not disclose all elements of independent claims 1, 14, and 43. The Examiner proposes to combine Grayzel et al. with Vigil et al. and Campbell et al. to obtain the missing elements. Specifically, the Examiner asserts that Vigil et al. can be combined with Grayzel et al. to add cutting elements to the outside of the balloon. Further, the Examiner asserts that Campbell et al. teaches adding a discrete strip of stiffening material extending the entire length of the balloon. The Examiner admits that the

references do not teach the cutting elements are centered over the striped portions, and asserts that it would have been obvious to determine this arrangement since it is one of a limited number of possible positions for the cutting elements to be located relative to the striped portions. However, Applicants submit that the cited references teach away from such an arrangement, thus making the claimed positioning non-obvious.

“A prior art reference must be considered in its entirety, i.e., as a whole, including portions that would lead away from the claimed invention. *W.L. Gore & Associates, Inc. v. Garlock, Inc.*, 721 F.2d 1540, 220 USPQ 303 (Fed. Cir. 1983), *cert. denied*, 469 U.S. 851 (1984).” (MPEP 2141.03 VI.). “When the prior art teaches away from combining certain known elements, discovery of successful means of combining them is more likely to be nonobvious.” *KSR*, 550 U.S. at \_\_\_, 82 USPQ2d at 1395. (MPEP 2143 A.).

Applicants direct the Examiner’s attention to Vigil et al. column 4, lines 8-13, where it is disclosed that when the balloon is collapsed, it will form alternating flaps and furrows, with the atherotomes (cutting elements) placed in the furrows to protect the blood vessel walls from damage. Attention is now directed to Campbell et al. column 5, lines 3-23 and Figures 2A-2B. Campbell et al. describe the effects of the discrete stripes (plastic material located within the lumens) being less stiff or more stiff than the balloon material. Specifically, Campbell indicates that in embodiments in which the plastic material is stiffer than the balloon walls (as currently claimed), Campbell teach that the balloon will form a shape depicted by Figure 2B when the balloon is collapsed. FIG. 2B is reproduced below.



**FIG.2B**

In this configuration, if cutting elements were centered over the stripes as claimed, the cutting elements would be on the outermost part of the balloon, and not disposed within

the furrows as specified by Vigil et al. This modification would run contrary to the express teachings of Vigil et al. Namely, this proposed modification would place the cutting elements in a location to produce significant damage to the blood vessel walls, a situation that would not be beneficial for the patient. Thus the combination asserted to be disclosed by the Examiner cannot be obtained from the cited references. Without the benefit of the Applicants' own application as a roadmap, one of ordinary skill in the art would not arrive at the claimed invention from the teachings of the cited references as the cited references teach away from the proposed modification.

Since the Examiner relies upon Vigil et al. and Campbell et al. to provide elements missing from Grayzel et al., and it is clearly evident that these references cannot be combined in a way that will produce the claimed invention, Applicants submit that the cited combination is inadequate to create a *prima facie* case of obviousness. Applicants submit that Grayzel et al., Vigil et al., and Campbell et al. do not disclose all elements of independent claims 1, 14, and 43, and cannot be properly combined to arrive at the claims. Therefore, claims 1, 14, and 43 are believed to be patentable over the cited references. Accordingly, claims 2-4, 6-13, 15-18, 20-34, 73-78, and 82-96, which depend from claims 1, 14, or 43 and add additional elements thereto, are also believed to be nonobvious in view of the cited references. Withdrawal of the rejections is respectfully requested.

#### **Response to "Response to Arguments"**

Page 6 of the Final Office Action states that Applicants argued "if the stiffening member were extended into the tapered portions of the balloon, the portions of the balloon with the stiffening members would not fold, thus creating a problem because the blade would not be collapsed." This is incorrect.

As discussed above, Applicants submit that the combination of references used to reach the claimed invention is improper because the references themselves teach away from their combination.

As seen in Figure 2B and discussed in column 3, line 65 to column 4, line 4, Campbell et al. teach that when the ribs or stiffening members (or the claimed discrete strips of a second material) have a higher stiffness than the balloon material (as is claimed), that the web of

balloon material between the ribs will collapse inward when the balloon is deflated, leaving the ribs at the outermost portion of the collapsed balloon.

As seen in Figure 2 and discussed in column 4, lines 9-13, Vigil et al. teach that when atherotomes (cutting blades) are present on the outside of a balloon, it is desirable to surround the blades with balloon material when the balloon is deflated so as to protect the vessel walls from contact with, and thus damage from, the blade edges.

As proposed in the Final Office Action, 8 stiffening members of Grayzel et al. are to be combined with 4 cutting blades of Vigil et al. with the blades centered over 4 of the 8 stiffening members, leaving 4 stiffening members without a blade disposed over them. The Examiner states that while neither Grayzel et al. nor Vigil et al. disclose or suggest positioning the blades over the stiffening members, it would be obvious to do so because of the limited number of possible positions available. The Examiner then proposes to include the teachings of Campbell et al. in order to extend the stiffening members into the tapered portions of the balloon. To the extent that such a combination is even possible, MPEP 2141.03 VI states: "A prior art reference must be considered in its entirety, i.e., as a whole, including portions that would lead away from the claimed invention. *W.L. Gore & Associates, Inc. v. Garlock, Inc.*, 721 F.2d 1540, 220 USPQ 303 (Fed. Cir. 1983), *cert. denied*, 469 U.S. 851 (1984)".

According to the Examiner's reasoning, Grayzel et al. and Vigil et al. have been combined to place cutting blades centered over stiffening members. Applicants note that Vigil et al. teach that cutting blades on the exterior surface of a balloon should be protected by the folds of the balloon during insertion to avoid damage to the vessel wall. However, as noted above, Campbell et al. teach that when the stiffening member has a higher stiffness than the balloon material, the material between the stiffening members will collapse leaving the stiffening members at the outermost portion of the collapsed balloon. Thus, one skilled in the art would not be led to combine these references to because Vigil et al. and Campbell et al. teach away from their combination, which in turn, precludes the stiffening members extending along the tapered portions of the balloon, as taught by Campbell et al.

Since the claims include the limitation of a cutting element centered over the discrete striped portion which has a higher stiffness than the balloon material, and the discrete strips

extending along at least a portion of the first and second tapered portions of the balloon, the cited references do not disclose or suggest each and every element of the independent claims, as is required to establish a *prima facie* obviousness rejection. Accordingly, Applicants respectfully request that the rejections be withdrawn.

**Conclusion**

Further examination and withdrawal of the rejections are respectfully requested. It is respectfully submitted that the claims are now in condition for allowance. Issuance of a Notice of Allowance in due course is requested. If a telephone conference might be of assistance, please contact the undersigned attorney at (612) 677-9050.

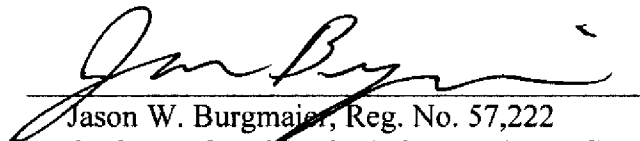
Respectfully submitted,

Lixiao Wang et al.

By their attorney,

Date: \_\_\_\_\_

Aug. 11, 2009



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